114.3 CMR 31.00: PRESCRIBED DRUGS

Section

31.01: General Provisions

(1) Scope, Purpose and Effective Date. 114.3 CMR 31.00 shall govern the determination of rates to be used by all governmental units for prescribed drugs dispensed to publicly-aided patients by eligible pharmacy providers. The rates set forth 114.3 CMR 31.04 shall be effective as of December 1, 2003. The rates set forth in 114.3 CMR 31.00 also apply to individuals covered by M.G.L. c. 152 (the Worker's Compensation Act) as set forth in 114.3 CMR 40.04(a)1.

(2) Coverage. 114.3 CMR 31.00 and the rates of payment contained herein shall apply to prescribed drugs dispensed by eligible pharmacy providers to publicly-aided patients. The rates of payment under 114.3 CMR 31.00 are full compensation for professional services rendered, as well as for any related administrative or supervisory duties.

(3) Authority. 114.3 CMR 31.00 is adopted pursuant to M.G.L. c. 118G and Chapter 26 of the Acts of 2003.

31.02: General Definitions

Actual Package Size. The package size of any drug for which a most frequently purchased package size has not been determined by the Division shall be the actual package size as indicated by the National Drug Code (NDC) listed on the container from which the pharmacist dispenses the drug.

Compounded Drug. Any drug, excluding cough preparations, in which two or more ingredients are extemporaneously mixed by a registered pharmacist.

Dispensing Fee. The fee paid, over and above the ingredient cost of the drug, to eligible pharmacy providers by governmental units and purchasers under the Worker's Compensation Act for dispensing prescribed drugs to publicly-aided individuals and/or industrial accident patients.

Drug. A substance containing one or more active ingredients in a specified dosage form and strength and authorized by the purchasing governmental unit or purchaser under M.G.L. c. 152. Each dosage form and strength is a separate drug.

Eligible Pharmacy Provider. Any pharmacy registered by the Board of Registration in Pharmacy in accordance with the provisions of M.G.L. c. 112 or a pharmacy in a clinic setting which has been licensed by the Department of Public Health in accordance with the provisions of M.G.L. c. 111 and which also meets the current conditions of participation of the purchasing governmental unit or purchaser under M.G.L. c. 152.

Estimated Acquisition Cost (EAC). An estimate of the price generally and currently paid by eligible pharmacy providers for the most frequently purchased package size of a drug. The EAC shall be the drug wholesaler's acquisition cost (WAC) plus 5 percent.

Federal Upper Limit. The Federal Upper Limit as established by the Centers for Medicare and Medicaid Services (CMS) in 42 CFR 447.332.

Fiscal Year. The annual accounting period adopted by an eligible pharmacy provider.

Governmental Unit. The Commonwealth, any department, agency, board or commission of the Commonwealth, and any political subdivision of the Commonwealth.

Legend Drug. Any drug for which a prescription is required by applicable federal and/or state laws or regulations.

Massachusetts Upper Limit. For multiple source drugs, an amount equal to one hundred thirty percent of the price of the least costly therapeutic equivalent as listed in any published or other public source for the most frequently purchased package size.

Most Frequently Purchased Package Size. The package size of a drug most frequently purchased by eligible pharmacy providers based on utilization data compiled by the Division of Medical Assistance (DMA). Thus, that NDC number which is most often paid by the DMA, and verified by audit, if necessary, will be considered the most frequently purchased package size.

Multiple Source Drug. A drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different names.

Non-Legend Drug. Any drug for which no prescription is required by federal or state law.

Provider. Anyone who furnishes services or supplies to publicly-aided and/or industrial accident patients for which he is entitled to reimbursement from a purchasing governmental unit or a purchaser under M.G.L. c. 152.

Publicly Aided Individual. A person for whose medical or other services a governmental unit is in whole or in part liable under a statutory public program.

Required Filing Date. The day by which all required reports must be submitted to the Division.

Required Reports. Any Division reports requesting data and information, including the Division of Health Care Finance and Policy's Massachusetts Pharmacy Costs report.

Single Source Drug. A drug marketed or sold by only one manufacturer or labeler under one proprietary name.

Unit-Dose Packaging. An individual drug product container usually consisting of foil, molded plastic, or laminate with indentations for a single solid oral dosage form, with any accompanying materials or components, including labeling. Each individual container fully identifies the drug and protects the integrity of the dosage. For purposes of 114.3 CMR 31.00, an assemblage of multiple, unlabeled single doses (traditional "bingo cards" or "bubble packs") is not unit-dose packaging.

Unit Dose-Return Fee. The fee paid to eligible pharmacy providers, by governmental units only, for accepting returned drugs in unit-dose packaging, as defined in 114.3 CMR 31.02, and in accordance with 130 CMR 406.446.

Usual and Customary Charge. The lowest price charged or accepted as payment for a given volume of drugs (legend or non-legend) by an eligible pharmacy provider to any purchaser or reimburser.

31.03: Filing and Reporting Requirements

(1) Required Reports and Records. Each eligible provider shall:

(a) file such data and information as the Division shall reasonably require.

(b) certify the accuracy and truthfulness of all data, information, reports, books, and records submitted to the Division.

(c) make available to the Division all reports, books, and records relating to its operation for audit.

(2) Filing Dates.

(a) All required reports and records shall be filed by eligible pharmacy providers with the Division within the time period specified by the Division in its request.
(b) The Division may, for cause, extend the filing date for submission of required reports and records.

(3) Reclassification of Eligible Pharmacy Providers. At the discretion of the Division, an eligible pharmacy provider may be placed in a category with a lower dispensing fee for failure to comply with 114.3 CMR 31.03(1) and (2).

(4) Penalties for Eligible Pharmacy Providers. In addition to reclassifying an eligible pharmacy provider, the Division may take other action against the pharmacy pursuant to its delegated powers under M.G.L. c. 118G.

31.04: Reimbursement Rates for Legend Drugs

(1) Reimbursement Rate for Multiple Source Drugs. Payment to eligible pharmacy providers for such drugs dispensed shall not exceed the lowest of:
(a) The federal upper limit of the drug, if any, plus the appropriate dispensing fee as listed in 114.3 CMR 31.07; or
(b) The Massachusetts upper limit of the drug, if any, plus the appropriate dispensing fee as listed in 114.3 CMR 31.07; or
(c) The estimated acquisition cost of the drug, plus the appropriate dispensing fee as listed in 114.3 CMR 31.07; or
(d) The usual and customary charge.

(2) Reimbursement Rates for All Other Drugs. These include single source drugs and brand name drugs which have been certified as medically necessary (i.e., for which the prescriber has designated "no substitution" and "brand name medically necessary" on the prescription form). Payment to eligible pharmacy providers for such drugs dispensed to publicly-aided patients shall not exceed the lower of:
(a) The estimated acquisition cost of the drug plus the appropriate dispensing fee as listed in 114.3 CMR 31.07; or
(b) The usual and customary charge.

(3) Rate Limitation. The rates determined under 114.3 CMR 31.04 shall not, in the aggregate, exceed the upper limits established pursuant to 42 CFR 447.331.

31.05: Reimbursement Rates for Non-Legend Drugs

Reimbursement Rate for Non-Legend Drugs. Payment to eligible pharmacy providers for a non-legend drug dispensed to a

publicly-aided patient or an industrial accident patient shall not exceed the lowest of:

(1) The Massachusetts Upper Limit of the drug plus the appropriate dispensing fee as listed in 114.3 CMR 31.07; or

(2) the estimated acquisition cost of the drug plus the appropriate dispensing fee as listed in 114.3 CMR 31.07; or

(3) the usual and customary charge.

31.06: Reimbursement Rates for Drugs Dispensed as part of an Innovative Program System for Publicly-Aided Patients

Government units may apply to the Division for approval of written contractual agreements containing programmatical and reimbursement provisions entered into with eligible pharmacy providers for drugs dispensed to publicly-aided patients. Approval of the contractual agreement by the Division shall constitute approval of the rates of payment set forth in the reimbursement provisions of the contract.

31.07: Dispensing and Return Fees

(1) Dispensing Fee - Prescribed Drugs. The dispensing fee paid to eligible pharmacy providers for dispensing prescribed drugs to publicly-aided and/or industrial accident patients shall be $3.00 per prescription.

(2) Dispensing Fee - Compounded Drugs. The dispensing fee paid to eligible pharmacy providers for dispensing prescribed compounded drugs to publicly-aided and/or industrial accident patients shall be the dispensing fee set forth in 114.3 CMR 31.07(1) plus:

(a) An additional $1.00 for:
1. compounding ointments or solutions; or
2. preparing solutions (excluding cough preparations) which involve the weighing of ingredients; or

(b) An additional $2.00 for:
1. compounding suppositories; or
2. compounding capsules, tablets, triturates or powders.

(3) Unit-Dose-Return Fee. The fee paid to eligible pharmacy providers for accepting returned drugs in unit-dose packaging, in accordance with 130 CMR 406.446, shall be $5.00 per unit-dose package.

31.08: Severability of the Provisions of 114.3 CMR 31.00

The provisions of 114.3 CMR 31.00 are severable, and if any provision of 114.3 CMR 31.00 or application of such provisions

to any eligible pharmacy provider or any circumstances shall be held to be invalid or unconstitutional, such invalidity shall not be construed to affect the validity or constitutionality of any remaining provisions of 114.3 CMR 31.00 or application of such provisions to any eligible pharmacy providers or circumstances other than those held invalid.

REGULATORY AUTHORITY

114.3 CMR 31.00: M.G.L. c. 118G.